# POSTSCRIPTS

Have you signed up for the AMWA Pacific Southwest Chapter Conference?

Registration is open!

See you in Old Town, San Diego May 1-2, 2015

## in this issue:
— Banish(ing) Words From our Language
— Typography in Medical Writing
— Paragraphs and Styles in Documents
— Technical Writing: A Primer

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# POSTSCRIPTS

## AIMS AND SCOPE

*Postscripts* magazine is the official publication of the Pacific Southwest chapter of the American Medical Writers Association (AMWA). It publishes news, notices and authoritative articles of interest in all areas of medical and scientific writing and communications. The scope covers clinical and regulatory writing, scientific writing, publication planning, social media, current regulations, ethical issues, and good writing techniques.

## MISSION STATEMENT

The mission of *Postscripts* is to facilitate the professional development of medical writers and serve as a tool to advance networking and mentoring opportunities among all members. Towards this mission, *Postscripts* publishes significant advances in issues, regulations and practice of medical writing and communications; skills and language; summaries and reports of meetings and symposia; and, book and journal summaries. Additionally, to promote career and networking needs of the members, *Postscripts* includes news and event notices covering Chapter activities.

**SUBSCRIPTION**:  *Postscripts* is published monthly except in January and July. The magazine is available as open access publication and is currently distributed online only.

**INSTRUCTION FOR CONTRIBUTORS**: We consider articles on any topic of interest to medical writers and communicators. It is helpful to look at the past December issues for year end table of contents, and browse past issues for style and type of articles published. We welcome contributions from AMWA members and non-members alike. Please contact editor.

**ADVERTISING**:  *Postscripts* is an advertising-free magazine. However, articles describing products and services relevant to medical writers may be considered or solicited. As a service to our members, they may submit advertisements for their services or products for free. Please contact editor.

**WEBSITES:**
*Postscripts*: http://issuu.com/postscripts
Chapter Website: http:// www.amwa-pacsw.org

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# Design and Medical Writing

"Anyone can claim to be a medical writer; the conundrum is to learn to be good at it, then to continue to work to be better," says Victoria White, the editor of *AMWA Journal*.[1] May I add that learning to apply the design principles will bring us one step closer to making our work much "better".

A good design is easy to spot in medical writing because it is functional. It blends art and text to get the message across: A research paper with easy to understand figures, tables, and graphics complementing the text, that can engage and inform the audience (the reader) would be a good example.

A good writer is also a designer and an illustrator. This issue of *Postscripts* has 3 articles devoted to the topic of Design Elements.

Dikran Toroser in his "AMA-zing Style" column (see page 51) describes the use of **typography** to achieve a balance of form and readability of text. Typography is defined as the arrangement and appearance of text that involves elements of design. A good design in an article involves judicious selection of the size and typeface of font(s), proper spacing between letters and lines, and appropriate margins to help maximize reader's attention.

The second article (page 53) by Susan Chang and and Francie Barron in the "de-MS-tifying Word" column explains how one can achieve typographic nirvana by using the **styles**, levels, and formatting options in the MS Word.

In some types of documents, such as, those in clinical or regulatory writing, the typographic and style choices are often agreed upon and locked down as standard, but as Christopher Walsh describes on page 49, technical writing requires one to be open to choices. Technical writers are jack of many trades developing research articles, grants, FDA submissions, how-to manuals, TED talks, cookbooks, textbooks, the contents of magazines, and textbooks. So, the best approach to learning about "design elements" in writing is to look up for resources in technical writing and graphic design. (The professional technical writers and graphic designers certainly know the best tricks.)

With the advent of tablets and apps, the written word on paper must also look equally good on the web (on computer) as well as on the tablet. It is helpful, therefore, to know the **CRAP principles**.[2] Use **contrast** to make different elements in writing stand out, and "be different"; use **repetition** of styles for connectedness, cohesiveness, and consistency across the document; **align** elements on the page, so they are "not out of place"; and make sure related elements are connected by **proximity**.

The AMWA free resource[3] is not to be missed here: "Guidelines for Document Designers" by Janice (Ginny) Redish, 2014. Redish lists 6 typographic principles, including highlighting, font sizes, line lengths, use of white spaces, and margins to help produce visually appealing and easy to read document. Redish writes, "well arranged text not only makes the document more inviting and physically easier to read, but can also aid the readers' understanding of the material.

— *Ajay K Malik, PhD*

1. AMWA J Spring issue 2015.
2. The Guidelines eBook is available free to AMWA members at: http://www.amwa.org/guidelines_doc_design
3. Read about CRAP Principles in: "Designing Business Information Systems: Apps, Websites, and More. 2012. " By Raymond D. Frost, Jacqueline C. Pike, Lauren N. Kenyo, Sarah E. Pels. Available at: http://2012books.lardbucket.org/books/designing-business-information-systems-apps-websites-and-more/index.html

# AMWA Pacific Southwest chapter warmly welcomes our new members

Gewnne Norcross – Rolling Hills

Kathleen Hopf – Oceanside

Mary Beth Sullivan – Los Angeles

Melvin Nutig – Beverly Hills

Sheldon Lazarow – Tucson, AZ

Swapnali Halder – Jonesboro, AR

(yes, Arkansas)

Wade Lovelace – Camarillo

List courtesy of Gail Flores, PhD, AMWA Pacific Southwest chapter membership coordinator.

# From the President's Desk

"Just living is not enough... One must have sunshine, freedom, and a little flower."
Hans Christian Andersen

Welcome to Spring!

Did you read the special 50th Anniversary chapter newsletter developed by our outstanding Newsletter Editor, Ajay Malik? Ajay received wonderful feedback about all of his work on this newsletter so please take a look – you will be happy you did!

We have fascinating articles in the newsletter this month. We thank Rebecca Andersen for keeping us updated about words that have been banished due to mis-use, over-use, and general uselessness. Christopher Walsh provides us with comprehensive overview about technical communication. Dikran Toroser always provides interesting articles and this month's article about typography is no exception. We can always learn from Susan Chang about tips and tricks in Word; this month, Susan teaches us how to use predefined styles. Lastly, we thank our employment coordinator, Sharyn Batey, for keeping us informed of jobs in the area.

We have been planning fun, interactive and educational events in our chapter. In March, we were lucky to hold an engaging webinar about pharmacokinetics given by Michelle Eggen and summarized by Jennifer Cossrow.

In April, please join us at one of our upcoming events:

April 2nd - Writers and Wine Networking, La Jolla, CA

April 3rd - Monthly chapter teleconference open to all medical writers in our chapter (12-1 pm PT, Dial-in: 323-920-0091, Attendee PIN: 020 4157)

April 11th - Saturday brunch in Chandler, AZ

April 23rd - Free Joint chapter webinar with the AMWA Northwest Chapter - Marcia Reinhart to present about Health Outcomes

And the big event for our chapter is our Pacific Southwest Chapter Conference in Old Town San Diego on May 1-2. Registration is now open!

For these events and other items about our chapter, please see our website, www.amwa pacsw.org, for more details.

We hope to see you this Spring,

*Donna*

Donna Simcoe, MS, MS, MBA, CMPP
President, AMWA Pacific Southwest Chapter

# List of Banished Words – 2015 Edition

## By **Rebecca J. Anderson, PhD**

Each year, the scholars at Lake Superior State University (LSSU) publish their list of words "Banished from the Queen's English for mis-use, over-use, and general uselessness." The LSSU word-watchers pull their pet peeves from various sources: everyday speech, the news, technology, advertising, and politics, among others. Here are a few of the words that they want banished this year. (I list them for your reference, in the unlikely event that you might be tempted to include them in your medical writing.)

**Polar vortex**: meteorologists use a lot of slang, but at least El Niño, Pineapple Express, and Nor'easter have clear definitions. Polar vortex is just another term for "winter."

**Hack**: this word already has too many meanings: (v.) to cut with unskillful blows, to gain unauthorized access to a computer, to cough; (n.) a worn out horse, a taxi, a writer of mediocre literary works. Now, "hack" has inexplicably also become a replacement for "tips" or "short cuts," as in home improvement hacks, painting hacks, and car hacks. There's even an eBook entitled *Marriage Hacks*, which congers up all sorts of mental images, depending on which definition of "hack" you choose. Enough, already!

**Skill set**: This is just another example of a needless expression. "Skill set" apparently sounds more posh than "skills," like saying "in close proximity to" when you mean "near." "Skills" works. Leave the "sets" to tennis and jazz musicians.

**Foodie**: when you use a word as a differentiator, but it includes the entire population of Earth, it's not very specific. Who doesn't like food?

**Curate**: this has become a fancy way of saying "selected," as in "curated monthly care packages that college students love." College kids may go for it, but does your pet really care about a box of curated doggie treats? Marketing gurus have embraced the word to fool online purchasers into thinking that their company's "curated mix" of products are special – really, they are just the things that failed to sell elsewhere. Let's give the term back to museums, where curators really do curate.

**Takeaway**: as in " What's your takeaway?" or "Is there any takeaway on that news?" "Takeaway" is bad enough when used for its original, parochial meanings. It's the British term for what we call take-out or to-go food orders. Here in the Colonies, it's a sports term, where one team is controlling the ball and the other team steals it, a takeaway. As for broadening its use, the LSSU scholars say, take away "takeaway."

**Enhanced interrogation**: a term invented by a government bureaucrat with too much time on his hands. You can't sugar-coat crime. To paraphrase Shakespeare, torture by any other name is still torture.

Details of this year's banished words and the full list from the last 40 years can be found on Lake Superior State University's website: www.lssu.edu/banished

They take nominations.

REBECCA J ANDERSON, PhD, is a freelance medical writer and the author of two books, *Nevirapine and the Quest to End Pediatric AIDS* and *Career Opportunities in Clinical Drug Research*. Prior to medical writing, Dr. Anderson managed research and development projects for twenty-five years in the pharmaceutical/biotech industry. She holds a Ph.D. in pharmacology from Georgetown University. She lives in Southern California, and when she is not writing, she absorbs the sights and sounds of the West Coast's rich culture and heritage. She can be reached at rebeccanderson@msn.com.

# Technical Communication – A Brief Primer

By **Christopher M. Walsh, PhD,** University of California San Diego

What do research articles, grants, FDA submissions, how-to manuals, TED talks, cookbooks, textbooks, the contents of magazines (such as *Popular Mechanics* and *Postscripts*), and textbooks have in common? -- These are all examples of technical communication.

Broadly speaking, technical communication includes any text or multimedia that teaches the audience.

## What is technical communication?

Technical communication is a transcriptional exercise where a technical writer starts with empirical data and transcribes that data into a story of scientific discovery. This communication may be formal or informal depending on the audience. For example, FDA submissions are extremely formal and matter-of-fact. For the technical writer, the FDA lists each required document for a submission, and the style for each document is established clearly. On the other hand, technical communication may appear very informal as in a science lesson plan for a third grade class, yet still deliver a clear message of a scientific observation, a principle, a discovery, etc.The unifying feature of technical communication is the objective reporting of empirical data.

## Which skills are necessary?

Technical communication is a broad field; thus, the skills of a technical communicator are equally broad. However, one does not need every skill to be a successful technical communicator. (After all, every technical writer selects a focus most attuned to his/her skill set and personal preference.) Nonetheless, there is a core set of skills that benefits a technical writer, including
- a love of science
- critical thinking skills (what does an experiment tell us, what are the limitations of an experiment)
- logical story progression (ignore the chronology of experiments; identify the salient points early and hammer the message and those points home)
- a broad interest in science
- independence
- resourcefulness (in the search for answers)
- visualization (science is complex)
- imagination (the subject of science writing may be invisible to the naked eye)

## What audience is served by a technical communicator?

The short answer is everyone. The targeted audience depends on the type of document and medium (print journals and magazines or web). Thus, the audience may include scientists, college graduates with a handful of science courses, business professionals, practitioners of law, technical communicators, journalists, and the general public with an interest in science but no formal training.  In fact, choosing the right audience and tailoring the documents and medium of delivery goes hand in hand with technical communication.

## Resources for learning about technical communication

Here is a brief list of professional organizations and web resources about the field of technical communication.

### *Major Organizations*
- Society of Technical Communication (www.STC.org)
- STC local chapter (www.STC-SD.org)
- American Medical Writers Association (www.AMWA.org)
- National Association of Science Writers (www.NASW.org)

### *Web Resources*
The websites for the professional organizations listed above provide a wealth of information. Each organization's website has a section describing technical communication as a discipline as well as links to additional resources. (I found a search with "recommended reading for technical writers" informative. The search results include both familiar texts [to me] and new references.) Additionally, Wikipedia has several entries under the "technical communication" umbrella, which serve as a good introductory text on this topic.  However, one should move on and dig deeper starting with the references listed in those wiki articles. Furthermore, many scientific journals (i.e. *Science, AMWA Journal,*

*Technical Communication*) include career profiles of technical communicators and general articles on technical communication in all its forms. One can start by searching for "technical communication" at the homepage of these journals. I found all these strategies very helpful as I embark on my own journey towards technical and medical writing.

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http://summit.stc.org

# AMA-zing Style — the AMA Manual of Style Column

By **Dikran Toroser, PhD, CMPP**, Amgen Inc., Thousand Oaks, Calif.

## Typography

The word font is connected to the art of typography (circa the 15th century). English-speaking printers (the human variety) used the term "fount" for many centuries to refer to the metal type used to assemble and print in a certain size and typeface. In the 80s, Steve Jobs merged this ancient art with the digital world, and made the 'font' ageless and beautiful.

In the AMA manual of style, typography is defined as the arrangement and appearance of text that involves elements of design. The editor and graphic designer often cooperate in the process of creating the typography with the goal of achieving a balance of form and readability. Good typography for English-language publications follows the linear flow of the Latin alphabet and supports the act of reading.[1]

English is read from left to right and from top to bottom. When a reader begins to read a printed page, the eyes first fall naturally to the top left corner and then move across and down the page, first from left to right and then in a right-to-left sweep to the next line, until reaching the bottom right corner. Any design or typographic element that forces the reader to work against this natural flow (the so called "reading gravity") interrupts the reading rhythm and should be avoided.[1]

In studies where half of the participants read an article with a design that followed "reading gravity" principles and half that did not, rates of comprehension in the presence of reading gravity were 67% and those reading the same article without reading gravity were ~32%.

**Basic Elements of Design** include:
- **Contrast:** The contrast between dark and light and large and small type (such as title and subheads).
- **Rhythm:** This refers to repetition of similar units, eg, spacing and proportion of type to the page.
- **Size:** The size of type and other elements affecting legibility and the overall appearance.
- **Color:** Color has 2 meanings: (1) the darkness of the type and (2) the use of colors attracting attention.

**Movement and Focal Points:** The elements of a page should guide the reader's eye along the lines of composition unconsciously, from large to small, from top to bottom, from left to right, from dark to light, and should follow the gravity of reading. In scholarly publishing, a number of typographic and design elements, such as prescribed text format, titles and headings, bylines, abstracts, tables, figures, lists, equations, block quotations, and reference citations and lists, must be considered and incorporated. The font for a publication typically includes generally 7 styles: roman lowercase letters, roman capitals (uppercase letters), boldface capitals, boldface lowercase letters, italic capitals, italic lowercase letters, and small capitals.

**Spacing and Letterspacing.** Readability of type depends on the spacing between letters, words, and lines; none of these is independent of the others. Letterspacing refers to the space between letters and other characters. There are no absolute values for optimal letterspacing, but type size and column width are interdependent in design and may affect reading comprehension.

**Word Spacing.** Typefaces have predetermined spacing between words that is dictated by the point size and width of a typestyle, the darkness or density of the typeface, and the openness or tightness of the letterspacing. For text set ragged right (unjustified), word spacing may be fixed and unchanging. However, for text that is set flush left and flush right (justified), the spacing may need to be more flexible.

**Line Spacing.** Line spacing refers to the vertical distance between the base of 1 line of text and the base of the next line of text. Line spacing is traditionally known as *leading* for the strips of lead once used between lines of printer type. Optimal line spacing requires consideration of the type size, layout density, and line length. Generally, longer lines call for increased line spacing for optimal readability.

**Layout.** Layout is the arrangement of all the elements of design and typography on the page for optimal readability, taking into account the context and aesthetic requirements of the text.

## Specific Uses of Fonts

**Lowercase.** Lowercase letters are smaller than capital (or uppercase) letters and are differently configured (eg, a, A).

The term *lowercase* originates from the earlier use of manually set wooden or metal characters that were kept by compositors in 2 cases; the lower case contained the smaller letters and the upper case contained the larger capital letters.

**Capital (Uppercase).** Use of all capital letters in large blocks of text should be avoided as legibility is decreased. A dropped cap (a form of initial cap) is an oversized capital letter of the first word that begins a paragraph and drops through several lines of text. It may be used in a complicated page to draw the reader's attention to the beginning of an article, chapter, or important section.

**Boldface.** A general scheme of heads and side heads may call for the use of boldface type for first- and second-level heads and for first-level side heads in the text, although heading styles and formats vary among journals. For example:

**METHODS** (level 1 head, flush left, bold caps)
**Statistical Analysis** (level 2 head, bold caps and lowercase)
**Clustering Data** (level 3 head or first-level side head, paragraph indent, run into the text, bold caps and lowercase).

**Italics.** Italics is a form of type style that slants to the right. Setting large blocks of text in italics should be avoided because legibility is reduced. Use italics as follows:

- For some non-English words and phrases. Do not use if words or phrases are considered to have become part of the English language, eg, cafe au lait, in vivo, in vitro, en bloc.
- For genus and species names of some microorganisms, plants, and animals (eg, *Staphylococcus aureus*)
- For portions of restriction enzyme terms (eg, *Taq*)
- For gene symbols but not gene names (eg, *mAAT*\*)
- For chemical prefixes (*N-* , *cis-*, *trans-*)
- For mathematical or some statistical expressions (*p*-value, *r2*)
- For the abbreviation for acceleration due to gravity, *g*, to distinguish it from g for gram.
- Sparingly, for *emphasis*

**Small Caps.** In this typeface style, all the letters take the shape of a capital letter. Small capital letters are used as follows:
- AM and PM in time
- BC, BCE, CE, and AD (Eras)
- Some prefixes in chemical formulas (L for levo-, 0 for dextro-)

See pages 917 to 927 in the AMA Manual of Style 10th edition for additional information.

## Acknowledgements

## REFERENCES

1. Wheildon C. Type & Layout: How Typography and Design Can Get Your Message Across-Or Get in the Way. Berkeley, CA: Strathmore Press; 1995.

## FURTHER READING

In the December 2014 issue\* of *Postscripts*, Deborah Meier Brown reviewed an eBook by Janice (Ginny) Redish, *Guidelines for Document Designers*. This little book offers tips on writing clear concise business documents, and is full of useful advice. AMWA members can access this eBook at the amwa.org website.
\**Postscripts* 2014;4(31):205-206

DIKRAN TOROSER, PhD, CMPP, a member of the AMWA Pacific Southwest chapter, is a regular contributor to the *Postscripts* magazine since 2012. He developed the monthly AMAzing Style column which covers topics from the AMA Manual of Style, and has also written on publication-related topics in these pages. Dikran is currently a Senior Medical Writing Manager at Amgen Inc. in Thousand Oaks, California. He earned his PhD in Biochemistry from Newcastle University (UK), and did his post-doctoral training in biochemical genetics at the John Innes Center of the Cambridge Laboratory (Norwich, UK) and in molecular biology with the USDA. Prior to Amgen, Dikran was on the faculty (research) at the School of Pharmacy at the University of Southern California. He can be reached at dtoroser@amgen.com.

# de-MS-tifying Word: Using Predefined Styles (Styles, Part 1)

### By **Susan Chang, PhD** and **Francie Barron, PhD**

I'm pleased to introduce a new contributor to this column, Francie Barron! Francie is a new member of the AMWA Pacific Southwest chapter, and she will be providing our Mac perspective.

*—Susan*

**Simplify, Organize, Declutter…**
As you've probably noticed, there are numerous blogs, eBooks, and magazine articles with advice on simplifying your life by organizing and decluttering your home and office. How can we apply these concepts to our documents?

You're likely dealing with one or more of these scenarios on a daily basis:
1 – Blank documents using the "Normal.dotx" defaults to drive formatting and styles.
2 – Commercially available documents running a different .dotx, such as "Author.dotx."
3 – Documents you've customized, either running Normal.dotx or your own .dotx.
4 – Previously developed documents that are reused often, with any (or all!) of these scenarios.

All of these scenarios (especially #4) have the potential to be very messy, "formattically" speaking. In the next few installments, we will explore how to organize, declutter, and simplify your documents.

**START YOUR YEAR WITH STYLE!**
Instead of reformatting text over and over again, you can use "styles" to apply predefined settings. This is a simple way to ensure clean, consistent formatting throughout your document.



Paragraph formatting (paragraphs defined by hard returns)

Character formatting (text within paragraphs)
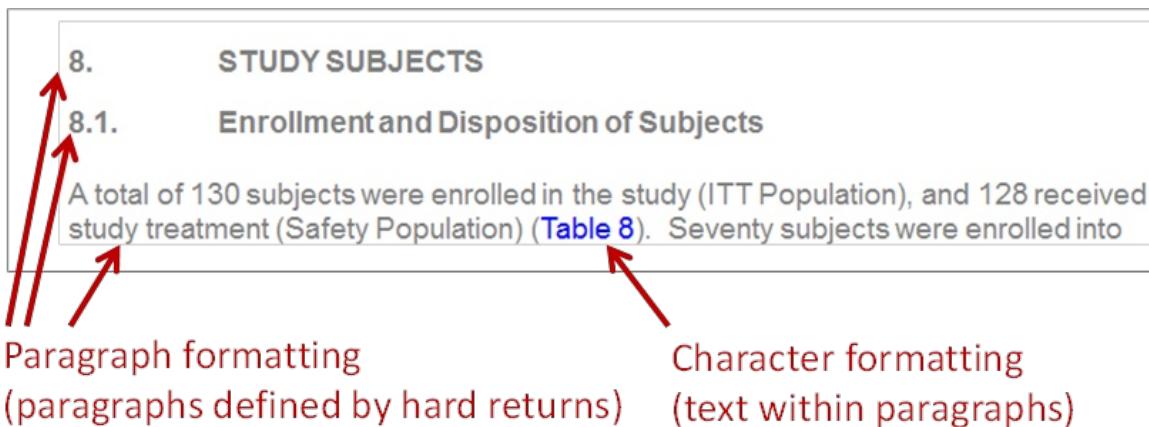
**Paragraph formatting options include:**
• left and right margins
• hanging indents and tabs
• space before/after a paragraph
• add numbering or bullets

**Character formatting options include:**
• font type
• size
• bold, plain, italicized
• lower case, upper case

MS Word provides several heading, body text, and list styles as a part of its default settings, which are based on the "Normal.dotx" document template.

**The BAD news**: MS Word defaults for text styles are just horrible.
**The GOOD news**: It's easy to modify styles to fit preferences, style guides, and journal requirements.

Using styles is easy. To begin, locate the styles available in your document via the Home tab:

## Quick Style Gallery



**Style Window**

1. **Highlight text of interest:**
   Learning how to use styles is really awesome.
2. **Click on the preferred style (eg, Body Text):**
   Learning how to use styles is really awesome.
3. **Smile because it's so easy!** ☺
4. **Explore other style options by launching the Style Window.**

Your preference
**Do not check!**
Your preferences

## THE BIG REVEAL – PCs

There are several ways to determine what styles are already in use in your document.
1. To inspect the formatting of a <u>specific selection of text</u>, simply click inside the text of interest and hit **SHIFT + F1** to reveal formatting to see paragraph- and character-level formatting details.
2. To view styles in an <u>entire document</u>, you can use the **Style Area Pane**. But first, you must change a Word default setting (you only have to do this once):
   (PC Word 2007) Office Button → Word Options → Advanced → Display → **Style Area Pane** = 1 inch
   (PC Word 2010) File tab → Options → Advanced → Display → **Style Area Pane** = 1 inch
…then choose **Draft View** in the **View tab** to reveal paragraph styles (you may need to zoom in).

Style Area Pane



**NOTE:** The Style Area Pane does not show styles for individual characters (eg, hyperlinks) or text within table cells, but "Reveal Formatting" does.

Reveal Formatting
Shift + F1

**THE BIG REVEAL – Macs**

1. To inspect the formatting of a <u>specific selection of text</u> (Mac Word 2011), Go to Menu bar → View →
   **Reveal Formatting** → select text of interest to show paragraph- and character-level formatting.
   To turn this function off, select Reveal Formatting again.
2. To view styles in an <u>entire document</u> on a Mac:
   - As with PCs, you can use the **Styles Area Pane**. First, change a Word default setting: (Mac Word 2011)
     Menu bar → Word → Preferences → Authoring and Proofing Tools → View → Window → Style Area
     Width = 1 inch. Then choose **Draft** under the **View** menu.
   - Select the **Show Styles Guides** within the Styles toolbox to reveal a color-coded legend for all styles in
     use (except for styles in floating images, floating objects, frames, or text boxes).
   - Select the **Show Direct Formatting** Guides within the Styles toolbox to highlight areas where the style
     has been manually "overridden" (eg, applying **bold**, *italics*, or color to a selection of text where "Body
     Text" style has been applied).

**TIP**: Show Style Guides and Show Direct Formatting Guides can be selected at the same time.
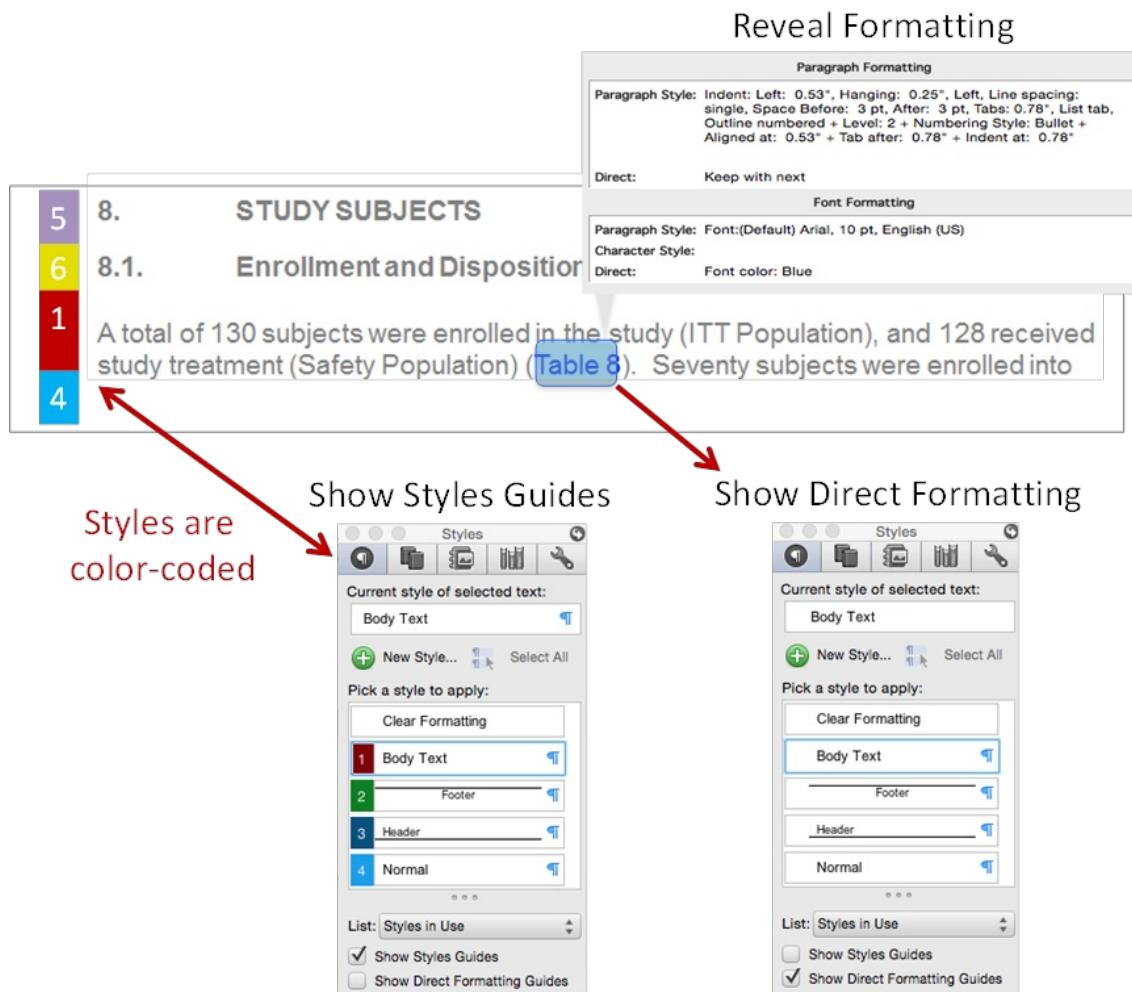


**Next month, learn how to modify existing styles and create new ones!**

# Evaluating and Reporting Pharmacokinetic Results in Clinical Trials

## By **Jennifer Cossrow**, AMWA Pacific Southwest Member

On February 25, 2015, a group of AMWA members attended a webcast entitled "Evaluating and Reporting Pharmacokinetic Results in Clinical Trials". Michelle Eggen, MA, a senior medical writer at Boehringer Ingelheim, shared with the attendees her experience and perspective on presenting pharmacokinetic (PK) data in clinical documents.

Collection of PK data is performed during all phases of a drug development program with the goal of selecting the optimal dose and dose regimen of a drug for the appropriate patient population. Understanding a drug candidate's PK properties is an essential component of drug development. In fact, PK issues represent the most common reason for drug failures in clinical studies.

Clinical studies are designed to determine the appropriate dose, posology, and formulation, to evaluate single and multiple dose PK, and to evaluate effects of intrinsic factors (eg, genetics, renal or hepatic dysfunction) or extrinsic factors (eg, drug-drug interactions) on PK. In PK studies or studies with a PK component, blood or urine samples are typically collected and analyzed in a bioanalytical lab to obtain concentration data. Concentration versus time data are analyzed using specialized software to calculate PK parameters, and the parameters are statistically analyzed to address the PK objectives of the study. In Phase 1 PK studies, typical objectives are to study initial PK in healthy volunteers, mass balance, safety and tolerability of escalating doses, bioavailability/bioequivalence, drug-drug interactions, food effect, or supporting a thorough QTc evaluation. Phase 2 studies include PK assessments to find the appropriate dose to demonstrate efficacy and to evaluate PK in special populations. A PK screen is also included in large Phase 3 efficacy trials.

### The Role of Medical Writer in Summarizing PK Data

Descriptions of objectives, methods, PK parameters, and statistical analysis were presented for each type of PK study, with a focus on the medical writer's role in reporting the data. For example, in a Phase 1 single ascending dose study, the objective is to determine the maximum tolerated dose (MTD) using a dose escalation design with careful safety monitoring. The parameters evaluated for each dose are maximum concentration ($C_{max}$), area under the concentration versus time curve (AUC), time of maximum concentration ($t_{max}$), and half-life ($t_{1/2}$) and statistics are primarily descriptive.

The medical writer therefore would present mean values for each parameter by dose in a table in the clinical document. Bioavailability/bioequivalence studies have the objective of comparing two formulations using a single-dose crossover design with serial blood sampling. Statistical analysis includes determination of the geometric mean ratio (GMR) and associated 90% CI for $C_{max}$, AUC, and $t_{max}$ for the two formulations. The two formulations are considered bioequivalent if the 90% CI of the GMR for $C_{max}$ or AUC is within 80%-120%, according the regulatory guidelines.

The medical writer would present this information in a table showing the geometric mean of each parameter for each formulation as well as the GMR and 90% CI, adding a brief statement indicating that the formulations are or are not bioequivalent with a reference to the table. Comparisons using GMR and 90% CI are similarly used in other types of studies, including studies to compare rate and extent of exposure in fed and fasted state or in different populations (eg, healthy and with renal impairment).

The medical writer's overall approach to presenting PK data in clinical documents is to know the study objectives, parameters of interest, and statistics of interest and to put the results in regulatory context.

The webcast also included a discussion of issues to consider when presenting clinical PK data. Data could be affected by protocol deviations such as out-of-window sampling, missed doses, or compliance issues. Descriptions of handling of missing, imputed, or below the level of quantification (BLQ) data are important as summary statistics could be affected by number of subjects in each group analyzed. In

general, the medical writer should pay attention to the number of subjects per group in case there are many subjects with missing doses or who dropped the study. Another point to consider is the impact on PK of vomiting or AEs leading to missed or reduced dose; vomiting within 2 hours of an oral dose is considered problematic for the PK evaluation in that subject. The medical writer should work closely with the PK scientist and statistician to ensure that PK data and conclusions are presented accurately and that any issues affecting the results are addressed in the clinical report.

JENNIFER COSSROW, PhD, is a medical writer with over 15 years experience in academic research and in drug discovery and development in the pharmaceutical industry, including 7 years of medical writing in the contract research organization setting. She is currently a Senior Medical Writer at Agility Clinical, a Carlsbad-based contract research organization. She holds a PhD in organic chemistry from University of California, Irvine. Prior to medical writing, she performed medicinal chemistry research with a focus on design and discovery of anticancer therapeutics.

Quest toward Brilliance | AMWA's 75TH ANNUAL CONFERENCE SEPTEMBER 30–OCTOBER 3, 2015 SAN ANTONIO, TX

http://www.amwa.org/events_annual_conference

# Medical Writing Open Positions

Compiled By: **Sharyn Batey, PharmD, MSPH**, PAREXEL International, San Diego

Employment Coordinator, AMWA PacSW Chapter

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**Medical Writer (6 month contract)**
Undisclosed Company, Santa Clara, CA
Recruiter Brenda Negron (bnegron@novellaclinical.com)

**Senior Medical Writer**
Halozyme Therapeutics, Inc., San Diego, CA
http://job-openings.monster.com/monster/de36219c-664b-4164-9a92-e15c2f78cf82?mescoid=2700440001001&jobPosition=2

**Technical Writer (Devices)**
Undisclosed Company (K-Force recruiting) San Diego, CA
https://www.kforce.com/Jobs/1696~WQG~1402131T1~99/?utm_source=Indeed&utm_medium=organic&utm_campaign=Indeed&id=2129

**Medical Writer**
Meridius Health Communications, Inc., San Diego, CA
Contact:  paula.soto@meridiushealth.com

**Medical Writer (Long Term Opportunity)**
Clarity Consultants, Thousand Oaks, CA
http://jobview.monster.com/Medical-Writers-Long-Term-Opportunity-Job-Thousand-Oaks-CA-US-146644926.aspx?mescoid=2700440001001&jobPosition=1

**Medical Communications Manager**
Amgen, Thousand Oaks, CA
https://sjobs.brassring.com/TGWebHost/jobdetails.aspx?jobId=1128986&partnerid=25236&siteid=5308&codes=JB_Indeed

**Medical Writing Manager**
Amgen, Thousand Oaks, CA
https://sjobs.brassring.com/TGWebHost/jobdetails.aspx?jobId=1126869&partnerid=25236&siteid=5308&codes=JB_Indeed

**Scientific Writer (Process)**
Peregrine Pharmaceuticals, Inc, Tustin, CA
http://www.biospace.com/jobs/job-listing/scientific-writer-process-341017

**Medical Writer**
Oncotherapeutics, West Hollywood, CA
http://www.oncotherapeutics.com/careers/medical-writer

If you want to share job leads with the members of the Pacific Southwest Chapter, please contact Sharyn at employment-coordinator@amwa-pacsw.org.

We are in the process of updating the jobs mailing list of chapter members who receive information about open medical writing positions during the month.  If you either want to either continue receiving the updates or to begin receiving the updates, please contact Sharyn at employment-coordinator@amwa-pacsw.org.

# Upcoming Chapter Events

**April 2nd** - Writers and Wine Networking, La Jolla, CA. We thank Real Life Sciences recruiters for co-hosting this free happy hour. Starts at 6:30 pm. Registration and details available at http://www.eventbrite.com/e/writers-and-wine-networking-with-amwa-and-real-life-sciences-tickets-16032572857

**April 3rd** - Monthly chapter teleconference open to all medical writers in our chapter (12-1 pm PT, Dial-in: 323-920-0091, Attendee PIN: 020 4157)

**April 11th** - Will you be in Arizona and would like to network with other medical writers? Amy Van Gels is hosting a Saturday brunch in Chandler, AZ (southeast Phoenix). Please contact Amy Van Gels (amy@AVGmedical.com) to register.

**April 23rd** - Free Joint chapter webinar with the AMWA Northwest Chapter about Health Outcomes. Marcia Reinhart, DPhil, Principal, Tantalus Medical Communications in Victoria, Canada will be presenting an engaging talk introducing writers to basic health economics and outcomes research (HEOR) concepts, and will provide some brief examples of opportunities for medical writing within this field. Registration and details available at https://www.eventbrite.com/e/health-economics-and-outcomes-research-basic-concepts-for-medical-writers-tickets-15347022357

**May 1 – May 2** - 2015 AMWA Pac-SW Conference, Courtyard Marriott San Diego.

**SAVE THE DATE!**

**2015 AMWA Pac-SW Conference**
May 1 – May 2, 2015

Courtyard Marriott San Diego, Old Town
2435 Jefferson St, San Diego 92110
www.oldtownsandiegoguide.com

Join us for small-group workshops, networking opportunities and provocative conversations with writers, editors, scientists, and other medical communicators in fun-filled and historic Old Town, home to numerous food, shopping, entertainment and cultural venues.

**Here's a taste of the open sessions:**

• Preparing a Clinical Study Report
• Setting up a Freelance Business
• Using Storytelling Skills to Tailor Communications for Different Audiences
• Medical communications careers (panel discussion)



**Plus 2 Workshops!**

• Outlining for Writers and Editors (ES/EW/FL) [2007], Sue Hudson
• Effective Paragraphing (ES/G) [2003], Helen Hodgson

**REGISTER HERE:**
www.amwa.org//calendar_day.asp?event=1545&date=5/1/2015

# Hans Christian Andersen



Statue in Central Park, New York, commemorating Andersen and The Ugly Duckling. Via Wikipedia Commons

April is the birth month of Hans Christian Andersen, a Danish storyteller famous for children books and fairy tales, such as, "The Little Mermaid", "The Snow Queen", "The Ugly Duckling", "The Nightingale", and "The Emperor's New Clothes." Andersen's birthday, April 2nd, is celebrated as International Children's Book Day.

The Hans Christian Andersen Center at the University of Denmark maintains a website with complete index of his work, translations of his writings, and research notes.

Closer to home, Solvang, California, a city founded by the Danish people, has a museum devoted to the work and art of Andersen. The Hans Christian Andersen Museum is operated by the Ugly Duckling Foundation, and is located upstairs in The Book Loft Building ( 1680 Mission Drive) in Solvang.

**Sources and Further Readings:**

University of Denmark: http://www.andersen.sdu.dk/index_e.html
Hans Christian Andersen: Fairy Tales and Stories: http://hca.gilead.org.il/
Wikipedia: http://en.wikipedia.org/wiki/Hans_Christian_Andersen
Hans Christian Museum in Solvang: http://www.solvangca.com/museum/h1.htm
Biography: http://www.biography.com/people/hans-christian-andersen-9184146

*—Editor*